October 1, 2008

Gail M. Hartwell
EH&S Improvement Specialist
Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268

Dear Ms. Hartwell:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 3,4-dichloro-alpha, alpha, alpha-trifluorotoluene posted on the ChemRTK HPV Challenge Program Web site on March 5, 2004 and October 6, 2005. I commend Dow AgroSciences LLC for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Dow AgroSciences advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. EPA has moved energetically from the HPV Challenge Program to the Chemical Assessment and Management Program, or ChAMP (www.epa.gov/champ), and is relying on Challenge chemical sponsors to provide, as expeditiously as possible, the data that are the key to this effort.

Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov. If you have any questions about this response, please contact me at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Mark W. Townsend, Chief
HPV Chemicals Branch

Enclosure

cc: O. Hernandez
R. Lee
J. Willis

EPA Comments on Chemical RTK HPV Challenge Submission:
3,4-Dichloro-α,α,α-trifluorotoluene

Summary of EPA Comments

The sponsor, Dow Agrosciences LLC, submitted a test plan, dated December 18, 2003, and robust summaries, dated August 24, 2005, to EPA for 3,4-dichloro-α,α,α-trifluorotoluene (3,4-dichloro-benzotrifluoride, DCBTF**,** CAS No. 328-84-7). EPA posted the submissions on the ChemRTK HPV Challenge Web site on March 5, 2004 and October 6, 2005, respectively.

EPA has reviewed this submission and has reached the following conclusions:

1. Physical Chemical Properties. Adequate data are available for melting point, boiling point, vapor pressure, and water solubility, although more details are needed. The submitter needs to provide a partition coefficient value.

2. Environmental Fate. Adequate data are available for biodegradation. The submitter needs to supply the data for the remaining endpoints.

3. Health Effects. Adequate data are available for acute and genetic toxicity. Limited information was submitted for the remaining endpoints. The submitter needs to provide separate robust summaries for repeated-dose and developmental toxicity, and an enhanced robust summary for reproductive toxicity, to permit a judgment of data adequacy.

4. Ecological Effects. Available data are adequate for the purposes of the HPV Challenge Program for fish and invertebrates. Although the algae data are flawed, EPA recommends no further testing.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the 3,4-Dichloro-α,α,α-Trifluorotoluene (DCBTF)
Challenge Submission

General

In 1987, DCBTF was the subject of a Testing Consent Order between EPA and then-manufacturer Occidental Chemical Corp. (52 FR 23547; June 23, 1987). The environmental effects and biodegradation studies in this HPV submission were performed pursuant to that Order.

Test Plan

Physical chemical properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

Adequate data are available for melting point, boiling point, vapor pressure, and water solubility for the purposes of the HPV Challenge program. Some clarifying information is needed for the robust summaries (see below under “Specific Comments on the Robust Summaries”).

Partition Coefficient. The submission did not include a partition coefficient. The submitter needs to provide this data point and summary.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

Adequate data are available for biodegradation for the purposes of the HPV Challenge program. Data were missing for the remaining endpoints. The submitter needs to supply the data that are lacking, including a technical discussion if it believes that stability in water testing is not necessary.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Adequate data are available for the acute toxicity and genetic toxicity endpoints.

Repeated-Dose Toxicity. The Repeated Dose Toxicity section of the IUCLID Data Set provided a robust summary for only one repeated-dose toxicity study (28-day feeding study in rats) with an adequate study duration (≥ 28 days). While the 28-day study was designated as "Critical study for SIDS endpoint", it was also assigned a Klimisch reliability code of 3 (invalid) owing to the potential for DCBTF to volatilize from the feed. Thus, the data from this study are inadequate to address the repeated-dose endpoint.

A robust summary of an unusual study protocol ("Modified 422") appears in the Toxicity to Reproduction section of the IUCLID Data Set. Male and female rats were dosed for 76-83 days (four weeks prior to mating, during mating, gestation and lactation) and so the study can be considered similar to an OECD TG 422 (combined repeated dose/developmental/reproductive toxicity study). The offspring from these parents were allowed to wean and then were exposed daily for 90 days via gavage to constitute another "repeated-dose" study, albeit with young animals (weaning age of rats is 20-24 days). Thus the protocol may satisfy the repeated-dose study requirement of the HPV Challenge Program. The robust summary does not present enough detail on what parameters were assessed or what effects were observed in terms of repeated-dose exposures in the adult/young animals. In order to allow a judgment of study adequacy, the submitter needs to provide a separate repeated-dose robust summary with the appropriate level of detail.

Reproductive and Developmental Toxicity. As noted in the *Repeated-Dose Toxicity* section above, a robust summary was provided in the Toxicity to Reproduction section of the IUCLID Data Set for a "Modified 422" gavage study. There was no indication that the reproductive and developmental toxicity parameters of OECD Test Guideline 422 (gestation length, number of live births, post implantation loss, number of runts, number of pups with grossly visible abnormalities, number of implantations, litter size, and litter weight) were examined. In order to allow a judgment of study adequacy the submitter needs to 1) supply more information in the robust summary for reproductive toxicity and 2) provide a separate robust summary for developmental toxicity.

Ecological Effects (fish, invertebrates, and algae)

Fish and invertebrates. Studies considered adequate for the purposes of the HPV Challenge Program are the acute toxicity studies with rainbow trout and fathead minnows [reference 8 in the robust summaries] and the invertebrate crustacean *Gammarus fasciatus* [reference 14 in the robust summaries]).

Algae. The submitted algae study is inadequate largely because over the course of the 96 hours there was > 99% loss of DCBTF and no effects were reported. Although losses of DCBTF were seen in other aquatic toxicity studies, they were smaller and effects were observed. Earlier, EPA's judgment on this study, performed pursuant to a Testing Consent Order, was that the volatility of DCBTF would probably cause similar difficulties in any repeat testing, and that the data for fish and invertebrates would be adequate to assess the ecotoxicological hazard in this case. Consistent with this judgment, EPA recommends no additional testing of DCBTF in algae for the purposes of the HPV Challenge Program.

Specific Comments on the Robust Summaries

The following comments apply to all the robust summaries. In general, the summaries did not provide enough detail, and often did not include test substance composition and identification. The submitter needs to follow EPA guidance (http://www.epa.gov/opptintr/chemrtk/pubs/general/guidocs.htm) for the preparation of robust summaries.

Physicochemical Properties

Melting Point, Boiling Point and Vapor Pressure. The submitter needs to provide specific information on the source of the reported values (beyond the MSDS as currently reported) and whether the values are measured or estimated. In the case of the vapor pressure value, units need to be stated.

Water Solubility. The value for this endpoint appears only in the "Method" field. It needs to appear in the "Value" field as well.

Health Effects

Repeated-Dose, Reproductive and Developmental Toxicity. The following missing information should be included in the robust summaries as appropriate for each endpoint: group size, organs weighed and examined histologically, statistical methods used (if any), and whether or not data were collected for the following parameters: hematology, clinical biochemistry, gestation length, number of live births, post implantation loss, number of runts, number of pups with grossly visible abnormalities, number of implantations, litter size, and litter weight.

Genetic Toxicity. Study details missing from the chromosomal aberrations robust summary include incidence and frequency of effects (the robust summary on p. 51 has a heading for this “Table 1”, but the data are not provided). This is important because the test was positive.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.